K013172
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DEC 2 0 2001

Section J: 510(k) Summary

PORGES™ Silicone prostatectomy catheter 510(k) submission

Ref. US1AB60A.DOC

Origin : Regulatory Affairs

PORGÈS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

J.1. Submitter's information

Submitter's name:	PORGES S.A.
Submitter's address:	Centre d'Affaires La Boursidière 92357 Le Plessis Robinson – France
Contact person:	Mr Bernard ISMAEL Regulatory Affairs Manager
Contact person's phone:	+ 33 1 46 01 32 06
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Contact person's email:	bernard.ismael@porges.com
Date of preparation:	July 2001

J.2. Device name

Classification name:	Urological Catheter, Retention type, Balloon (78 EZL)
Common / Usual name:	Prostatectomy catheter
Proprietary name:	PORGES™ Silicone prostatectomy catheter

J.3. Predicate devices

The PORGES™ Silicone prostatectomy catheter is substantially equivalent to the modified paediatric silicone Foley catheter from PORGES and to the Bardex® All-silicone 3-way Foley catheter from BARD.

J.4. Description of the Device

The PORGES™ Silicone prostatectomy catheter is a balloon catheter of the retention type, commonly called a Foley catheter. It is made of medical grade extruded transparent silicone elastomer with a radiopaque stripe. The device is a single use, disposable, sterile with retention balloon, which is attached to the silicone shaft. One lumen is for draining fluids to and from the urinary tract. The second lumen is to inflate and deflate the balloon with sterile water. On models with a third lumen, it is used in conjunction with the first lumen for irrigation the urinary tract. Sterile water is used for inflation and deflation of the balloon. The distal end has opposite eye holes, which are used for drainage.
Nominal balloon inflation volumes are 15 to 30 cm^3 or 30 to 50 cm^3 with the 15 to 30 cm^3 balloon being used to hold the catheter in place for normal usage, and 30 to 50 cm^3 when a larger balloon is indicated.
On the opposing end of the shaft, are an connecting funnel and a Luer activated valve of which the colour varies according to the size of the catheter.
This product is available in sizes 18 Fr to 24 Fr, with DUFOUR, DELINOTTE, COUVELAIRE or standard tip.
Total length of all catheters : 42 cm. One catheter has an open tip to fit over a guide wire.

J.5. Intended use of the Device

The PORGES™ Silicone prostatectomy catheter is used for :

- short term drainage of the vesical urines,
- irrigation/injection and drainage following surgery,
- after prostate surgery : hemostasis of the prostate area.

J.6. Technological characteristics

The PORGES™ Silicone prostatectomy catheter has similar technological and performance characteristics to the predicate devices. The catheter is manufactured entirely from silicone elastomer as for the predicate devices. The catheter is supplied in French sizes ranging from 18 to 24 and balloon capacities 15-30 cm^3 to 30-50 cm^3. The predicate device are available in French sizes from 6 to 26 balloon capacities from 1.5 cm^3 to 30 cm^3. The device is supplied in male length only. The predicate device is supplied in male and female lengths. All of the devices are supplied sterile for single use.

J.7. Testing and results

The PORGES™ Silicone prostatectomy catheter referenced in this submission is held to the same design, manufacture, and performance specifications as those Foley catheters currently manufactured. Performance and functional testing standards are based on the FDA "Guidance for the content of premarket notifications for conventional and antimicrobial Foley catheters" dated September 12, 1994.
The PORGES™ Silicone prostatectomy catheter meets the following performance requirements per testing conducted according to ASTM F 623-89, when appropriate, and/or PORGES testing/acceptance criteria:

Note: ASTM F 623-89 excludes from the scope the catheters that have three lumens, balloons equal to or larger than 30 cm^3. However, the test methods described therein will also be utilised to test tri-lumen (3-way) catheters, balloon catheters equal to or larger than 30 cm^3.

- Flow rate through the drainage lumen
- Resistance of the balloon to rupture when inflated to the claimed balloon volume and held under conditions approximating the usage environment for a period of seven days;
- Resistance of the inflated balloon to being distorted and pulled through the bladder outlet;
- Maintenance of balloon inflation to fill volume over an extended time;
- Manufacturing tolerances for catheter tip, balloon and shaft diameters;
- Ability of an inflated catheter that has been submerged for seven days to deflate reliability to within 4 Fr. sizes of the labelled shaft size, as applicable, including the time for such deflation;
- Shaft tensile strength and tip adherence;
- Balloon burst.

The PORGES™ Silicone prostatectomy catheter passes biocompatibility testing per ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Bernard Ismael
Regulatory Affairs Manager
PORGÈS-C.A. La Boursidière
92357 Le Plessis Robinson
CEDEX FRANCE

Re: K013172
Trade/Device Name: Porges Silicone Prostatectomy Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessori
Regulatory Class: II
Product Code: 78 EZL
Dated: September 21, 2001
Received: September 24, 2001

Dear Mr. Ismael:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section F: Indications for Use Statement

510(k) Number (if known): K013172

Device Name: PORGES™ Silicone prostatectomy catheter

Indications for use:

The PORGES™ Silicone prostatectomy catheter is used for :

- short term drainage of the vesical urines,
- irrigation/injection and drainage following surgery,
- after prostate surgery : hemostasis of the prostate area.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013172